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RE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,117	04/02/2004	Ruben G. Carbonell	S1821-0111 (51821-299533)	3952
23370	7590	12/28/2005	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			WINKLER, ULRIKE	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/817,117	CARBONELL ET AL.
	Examiner Ulrike Winkler	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-49 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____ .

**DETAILED ACTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-6, 9-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of an amine group, classified in class 524, subclass 722.
2. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of a sulfite group, classified in class 558, subclass 59.
3. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of sulfonyl group, classified in class 522, subclass 59.
4. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of a tresyl group, classified in class 520, subclass 1.
5. Claims 1-6, 8, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of an alkyl group, classified in class 524, subclass 46.
6. Claims 1-7, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of an aromatic group, classified in class 524, subclass 471.
7. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of a siloxane group, classified in class 524, subclass 731.
8. Claims 1-6, 12-33 drawn to a method of forming a complex with a prion protein using a binding material comprising a functional group made up of a fluorinated group, classified in class 524, subclass 795.
9. Claims 34-49 drawn to a method of forming a complex with a prion protein using a binding material comprising aluminum, classified in class 424, subclass 682.
10. Claims 34-49 drawn to a method of forming a complex with a prion protein using a binding material comprising silica, classified in class 424, subclass 704.

For each of invention sets 1-10 above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of **inventions 1-10 and** one of inventions (A1)-(D1). Applicants need to select what form of the prion protein is to be detected by their binding method.

- (A1). PrPc.
- (B1). PrPSc.
- (C1). PrPr.
- (D1). PrPres.

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For each of invention sets 1-8 above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of **inventions 1-8** and one of inventions (A1)-(D1). Applicants need to select a single polymer matrix that is used in the method.

- (A2). Polymethylacrylate (TOYOPEARLTM Amino 650 ?), classified in class 429, subclass 317.
- (B2). Methylacrylate (TOYOPEARLTM Amino 650 ?), classified in class 524, subclass 329.7.
- (C2). FRACTOGEL™ EMD, classified in class 520, subclass 1.
- (D2). TOYOPEARL™, classified in class 520, subclass 1.
- (E2). TSK-GEL™, classified in class 520, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions (A1)-(D1) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different prion polypeptides. Therefore, where structural identity is required, such as for detection or disease prognosis, the different structures represented by the same sequences have different effects.

Inventions (A2)-(E2) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent different polymer matrixes. Therefore, where structural identity is required, such as for binding a particular form of the prion protein, the different structures represented by different matrixes have different binding effects on the prion protein.

Inventions (1)-(10) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent different functional groups. Therefore, where structural identity is required, such as for binding a particular prion protein the different functional groups have different effects.

Claim 1 link(s) inventions (A1)-(D1). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable

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linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 34 link(s) inventions (A1)-(D1). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to the following patentably distinct species of the claimed invention:

- (SA3). human.
- (SB3). bovine.
- (SC3). ovine.
- (SD3). porcine.
- (SE3). equine.
- (SF3). murine.
- (SG3). cervidae.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- (S1). Biological sample: blood derived sample
- (S2). Biological sample: brain derived sample
- (S3). Biological sample: bodily fluid derived sample

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- (S4). Biological sample: collagen extract
- (S4). Biological sample: gland extract.
- (S6). Biological sample: tissue homogenate or extract.
- (S7). Food product/food/or nutritional supplement.
- (S8). Environmental product.
- (S9). Water sample.
- (S10). Pharmaceutical compositions.
- (S11). Therapeutic composition.
- (S12). cosmetic composition.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims directed to "the sample" are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.



ULRIKE WINKLER, PH.D.  
PRIMARY EXAMINER 12/23/05